

§ 203.23

21 CFR Ch. I (4–1–12 Edition)

(a) The purchase or other acquisition of a drug for its own use by a hospital or other health care entity that is a member of a group purchasing organization from the group purchasing organization or from other hospitals or health care entities that are members of the organization.

(b) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control.

(d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons.

(e) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a valid prescription.

(f) The sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug by hospitals or health care entities owned or operated by Federal, State, or local governmental units to other hospitals or health care entities owned or operated by Federal, State, or local governmental units.

(g) The sale, purchase, or trade of, or the offer to sell, purchase, or trade blood or blood components intended for transfusion.

(h) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a registered blood establishment that qualifies as a health care entity any:

(1) Drug indicated for a bleeding or clotting disorder, or anemia;

(2) Blood collection container approved under section 505 of the act; or

(3) Drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative); as long as all of the health care services that the establishment provides are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested to-

gether with specimens undergoing routine donor testing. Blood establishments relying on the exclusion in this paragraph must satisfy all other requirements of the act and this part applicable to a wholesale distributor or retail pharmacy.

(i) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act and that qualifies as a health care entity, any drug indicated for a bleeding or clotting disorder, or anemia, or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative). Comprehensive hemophilia diagnostic treatment centers relying on the exclusion in this paragraph must satisfy all other requirements of the act and this part applicable to a wholesale distributor or retail pharmacy.

[64 FR 67756, Dec. 3, 1999, as amended at 73 FR 59500, Oct. 9, 2008]

§ 203.23 Returns.

The return of a prescription drug purchased by a hospital or health care entity or acquired at a reduced price by or donated to a charitable institution is exempt from the prohibitions in § 203.20, provided that:

(a) The hospital, health care entity, or charitable institution documents the return by filling out a credit memo specifying:

(1) The name and address of the hospital, health care entity, or charitable institution;

(2) The name and address of the manufacturer or wholesale distributor from which it was acquired;

(3) The product name and lot or control number;

(4) The quantity returned; and

(5) The date of the return.

(b) The hospital, health care entity, or charitable institution forwards a copy of each credit memo to the manufacturer and retains a copy of each credit memo for its records;

(c) Any drugs returned to a manufacturer or wholesale distributor are kept under proper conditions for storage, handling, and shipping, and written documentation showing that proper conditions were maintained is provided

to the manufacturer or wholesale distributor to which the drugs are returned.

Subpart D—Samples

§ 203.30 Sample distribution by mail or common carrier.

(a) *Requirements for drug sample distribution by mail or common carrier.* A manufacturer or authorized distributor of record may distribute a drug sample to a practitioner licensed to prescribe the drug that is to be sampled or, at the written request of a licensed practitioner, to the pharmacy of a hospital or other health care entity, by mail or common carrier, provided that:

(1) The licensed practitioner executes and submits a written request to the manufacturer or authorized distributor of record, as set forth in paragraph (b) of this section, before the delivery of the drug sample;

(2) The manufacturer or authorized distributor of record verifies with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product;

(3) The recipient executes a written receipt, as set forth in paragraph (c) of this section, when the drug sample is delivered; and

(4) The receipt is returned to the manufacturer or distributor from which the drug sample was received.

(b) *Contents of the written request form for delivery of samples by mail or common carrier.* (1) A written request for a drug sample to be delivered by mail or common carrier to a licensed practitioner is required to contain the following:

(i) The name, address, professional title, and signature of the practitioner making the request;

(ii) The practitioner's State license or authorization number or, where a scheduled drug product is requested, the practitioner's Drug Enforcement Administration number.

(iii) The proprietary or established name and the strength of the drug sample requested;

(iv) The quantity requested;

(v) The name of the manufacturer and the authorized distributor of record, if the drug sample is requested

from an authorized distributor of record; and

(vi) The date of the request.

(2) A written request for a drug sample to be delivered by mail or common carrier to the pharmacy of a hospital or other health care entity is required to contain, in addition to all of the information in paragraph (b)(1) of this section, the name and address of the pharmacy of the hospital or other health care entity to which the drug sample is to be delivered.

(c) *Contents of the receipt to be completed upon delivery of a drug sample.* The receipt is to be on a form designated by the manufacturer or distributor, and is required to contain the following:

(1) If the drug sample is delivered to the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner's designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample and the quantity of the drug sample delivered; and the date of the delivery.

(2) If the drug sample is delivered to the pharmacy of a hospital or other health care entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or health care entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

§ 203.31 Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).

(a) *Requirements for drug sample distribution by means other than mail or common carrier.* A manufacturer or authorized distributor of record may distribute by means other than mail or common carrier, by a representative or detailer, a drug sample to a practitioner licensed to prescribe the drug to